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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FLOOD, MICHELE C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,585

Applicant(s)

KADOTA ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 8 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8 and 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 20, 2006 and the declaration under 37 C.F.R. 1.132 by Chia-Chin Sheu. Further acknowledgment is made of Applicant's cancellation of Claims 9-20 and the addition of newly submitted Claims 21-29.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Newly submitted Claims 7, 8, 27, 28 and 29 are directed to invention that are independent or distinct from the invention originally claimed for the following reasons: the subject matter of the originally presented claims was directed to a composition for treating osteoporosis comprising *Cordyceps sinensis* or the processed extract product of *Cordyceps sinensis* as an effective ingredient, whereas the subject matter of newly submitted Claims 7, 8, 27, 28 and 29 is directed to a composition for treating osteoporosis comprising an organic solvent extract product of culture of *Cordyceps sinensis*, wherein at least one organic solvent is diethyl ether and a method of use thereof; as well as, a method of treating osteoporosis comprising a composition of Claim 1, namely a composition comprising a dried powder of culture of *Cordyceps sinensis*. Moreover, the subject matter of the originally elected invention encompassed the species election of the water extract of the claim-designated ingredient of *Cordyceps sinensis*; and, nowhere in the previous presented claims did Applicant direct the subject

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matter to a method of using any of the claim designated compositions. Furthermore, the product as claimed in the invention of Group I, Claims 1-3, can be used in a materially different process of using that product, as evidenced by the teachings of the prior art set forth in the rejections made under 35 U.S.C. § 102 set forth below. See MPEP § 806.05(h).

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly Claims 7, 8, 27, 28 and 29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-3 are under examination.

Claim Objections

Claims 1 and 3 are objected to because of the following informalities: There is an apparent misspelling in line 2 of each of the claims. Applicant may overcome the objection by replacing "*Cordycepes*" with *Cordyceps*. Newly applied as necessitated by an obvious typographical error considering that the term was correctly spelled in the originally presented claims.

Appropriate correction is required.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Taketomo et al. (A*) and Yoshii (N). Newly applied as necessitated by amendment.

Applicant claims a composition for treating osteoporosis comprising a dried powder of culture of *Cordyceps sinensis* as an effective ingredient. Applicant further claims the composition according to claim 1, wherein the composition treats osteoporosis by suppressing a decrease of spongy bone density; and, wherein the *Cordyceps sinensis* is mycelium of *Cordyceps sinensis*.

Taketomo teaches a composition comprising a dried powder of culture of mycelium of *Cordyceps sinensis*. See Column 3, lines 46-48.

Taketomo does not teach the referenced fungal extract as a composition for treating osteoporosis or as a composition for suppressing the decrease of spongy bone density. However, the claimed functional effects are considered inherent to the extract taught by Taketomo because the fungus and the part of the fungus used in the making of the *Cordyceps sinensis* extract are one and the same as disclosed in the instantly

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claimed invention of Applicant. Thus, a composition for treating osteoporosis comprising a dried powder culture of mycelium of *Cordyceps sinensis* as an effective ingredient, wherein the composition treats osteoporosis by suppressing a decrease of spongy bone density is inherent to the composition taught by Taketomo.

Yoshii teaches a composition comprising a dried powder of culture of mycelium of *Cordyceps sinensis*.

Yoshii does not teach the referenced fungal extract as a composition for treating osteoporosis or as composition for suppressing the decrease of spongy bone density. However, the claimed functional effects are considered inherent to the extract taught by Yoshii because the fungus and the part of the fungus used in the making of the *Cordyceps sinensis* extract are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, a composition for treating osteoporosis comprising a dried powder culture of mycelium of *Cordyceps sinensis* as an effective ingredient, wherein the composition treats osteoporosis by suppressing a decrease of spongy bone density is inherent to the composition taught by Yoshii.

Each of the references of Taketomo and Yoshii anticipates the claimed subject matter.

Claims 1 and 2, as amended, are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al. (P, CN 1356115 A, Translation of foreign language patent provided herein.). Newly applied as necessitated by amendment.

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Applicant's claimed invention of Claims 1 and 2 was set forth above.

Li teaches a composition comprising a dried powder of culture of *Cordyceps sinensis*.

Li does not teach the referenced fungal extract treats osteoporosis by suppressing the decrease of spongy bone density. However, the claimed functional effect is considered inherent to the extract taught by Li because the fungus used in the making of the Li' composition is one and the same as disclosed in the instantly claimed invention of Applicant. Thus, a composition for treating osteoporosis comprising a dried powder culture of mycelium of *Cordyceps sinensis* as an effective ingredient, wherein the composition treats osteoporosis by suppressing a decrease of spongy bone density is inherent to the composition taught by Li.

The reference anticipates the claimed subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9 and 10 of copending Application No. 11/533,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of one another. Newly applied as necessitated by recent filing, that is after the mail date of the previous Office action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 11, 2006